# 510(k) Summary

K102944

**Introduction**

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

**Submitter name, address, contact**

Roche Diagnostics
9115 Hague Road, P.O. Box 50416
Indianapolis, IN 46250-0416
317-521-3501

AUG 3 1 2010

Contact Person: Kelly Colleen O'Maine Adams
Phone: 317-521-3577
Fax: 317-521-2324
Email: colleen.adams@roche.com

Secondary Contact: Stephanie Greeman
Phone: 317-521-2458
Fax: 317-521-2324
Email: stephanie.greeman@roche.com

Date Prepared: July 20, 2010

**Device Name**

Proprietary name: Elecsys Digoxin CalCheck 5
Common name: Digoxin CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

**Predicate device**

The Elecsys Digoxin CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys Digoxin CalCheck (K973973).

**Device Description**

The Elecsys Digoxin CalCheck 5 is a liquid product consisting of Digoxin in a buffer/protein (bovine serum) matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

**Intended use**

The Elecsys Digoxin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Digoxin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

*Continued on next page*

**Comparison Table** The table below compares Elecsys Digoxin CalCheck 5 with the predicate device, Elecsys Digoxin CalCheck (K973973).

| **Characteristic** | **Elecsys Digoxin CalCheck 5 (Candidate Device)** | **Elecsys Digoxin CalCheck (K973973)** |
|---|---|---|
| Intended Use | The Elecsys Digoxin Calcheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Digoxin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. | For use in the verification of the calibration established by the Elecsys Digoxin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers. |
| Analyte | Digoxin | Digoxin |
| Levels | Five | Three |
| Format | Liquid | Liquid |
| Handling | Mix gently by inversion to ensure homogeneity. | Mix gently by inversion to ensure homogeneity. |
| Stability | Unopened:<br>• Store at 2-8°C until expiration date<br>Opened:<br>• 20-25°C: 6 hours | Unopened:<br>• Store at 2-8°C until expiration date<br>Opened:<br>• 15-25°C: 5 hours |
| Matrix | Bovine serum matrix | Bovine serum matrix |

**Performance Characteristics** The Elecsys Digoxin CalCheck 5 was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Roche Professional Diagnostics
Ms. Kelly Colleen O'Maine Adams
9115 Hague Road
Indianapolis, IN 46250-0416

AUG 3 1 2010

Re: k102044
Trade/Device Name: Elecsys Digoxin CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: 20 July, 2010
Received: 21 July, 2010

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or ( 301 ) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): K102044

Device Name: Elecsys Digoxin CalCheck 5

Indication For Use:

The Elecsys Digoxin CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys Digoxin reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102044